

### Remarks

Applicants note the withdrawal of finality of the previous Office Action. In accordance with the Examiner's helpful suggestion, the Applicants have added new claim 36 drawn to an immunogenic composition comprising a protein according to Claim 5 and a pharmaceutically acceptable carrier.

### Claim Rejections under 35 U.S.C. § 112

Claims 33 and 34 have been rejected under 35 U.S.C. § 112, first paragraph. Applicants respectfully submit that the Specification, along with general knowledge in the art, readily provides one skilled in the art the requisite knowledge necessary to produce the Applicants' claimed pharmaceutical composition. The interpretation of Plotkin is inapplicable in view of the Applicants' Specification. Applicants respectfully submit that the Specification clearly illustrates that the inventors have discovered that the claimed protein, SEQ ID No. 1, elicits the production of protective antibodies and thus causes an immunogenic response. Therefore, the Applicants have identified the protein component of three separate pathogenic microsporidia which elicit the production of protective antibodies.

As is well known in the art, an antibody is a protein that is produced in response to an antigen (often a virus or bacterium). It is able to combine with and facilitate the clearance of the antigen. It is common knowledge to those of less than ordinary skill in the art that antibodies provide protection against attack by a pathogen. Simply put, this concept has been a premise of vaccination for many years. For the Examiner's convenience, the Applicants enclose herewith a definition of antibody, taken from Kuby. J, *Immunology*, 2003. Example 1 describes the production of two polyclonal antibodies and a monoclonal antibody, which were produced and secreted when the Applicants' claimed polar tube protein was injected into mice. Secreted

antibodies are the major effector molecules of humoral immunity. As can be seen in Fig. 1, the Applicants used immunofluorescence and electron microscopy to demonstrate that the Applicants' newly discovered polyclonal antibodies and monoclonal antibody reacts specifically with the Applicants' polar tube proteins.

The inventors have identified the microsporidian proteins (e.g. the polar tube proteins) of the genus *Encephalitozoon* as "the protein component of a microbial pathogen that itself can elicit the production of protective antibodies... and thus protect the host against attack by the pathogen." Consequently, the inventors have overcome the hurdles described by Plotkin. Contrary to the helpful comments in the Official Action, Plotkin does not make the Applicants' claim unpredictable, because the inventors have described and demonstrated that the claimed proteins do in fact elicit the production of antibodies. As is well known in the art, the fundamental concept of vaccination is the production of antibodies to protect against infection from pathogens. In view of the foregoing, one skilled in the art can readily practice the invention without undue experimentation.

The Specification clearly explains that the claimed proteins elicit the production of antibodies. One skilled in the art can easily prepare the Applicants' protein as explained in Example 1 and inject the protein into mice to obtain antibodies following standard immunology protocol. Little, if any, experimentation is required, much less undue experimentation. Further, Example 1, page 17, lines 13-14 illustrates that three antibodies directed against the polar tube protein were in fact obtained. Keeping in mind that the fundamental function of antibodies is to protect from infection, the Applicants respectfully submit that a working example (Example 1) is set forth. Applicants respectfully request withdrawal of the rejection of Claims 33-34, under 35 U.S.C. § 112, first paragraph.

**Claim Rejections Under 35 U.S.C. § 102(b)**

Applicants respectfully submit that the rejection of claims 2 to 4 and 33 to 34 under 35 U.S.C. § 102(b) are moot in view of the Applicants' claim amendments. In accordance with the Examiner's helpful suggestion, the Applicants have amended Claim 5 to place it in independent form and further amended Claims 33-35, to depend from Claim 5. Withdrawal of the rejection of Claims 33 to 35 under 35 U.S.C. § 102(b), first paragraph is respectfully requested.

In view of the foregoing the Applicants respectfully submit the Application is now in condition for allowance, which is respectfully requested.

Respectfully submitted,

  
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